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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/542,520	04/03/00	JACKSON W	7969-076-999

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EXAMINER	
SPIEGLER, A	
ART UNIT	**PAPER NUMBER**
1656	9

DATE MAILED: 06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/542,520	JACKSON ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1656	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 16-17, 19-20, 25, 30-31, and 38-39, drawn to a HMW protein and compositions containing said protein, classified in class 530, subclass 350, for example.

II. Claims 7-15, 18-19, 20, 25, 30-31, and 41, drawn to nucleic acids, vectors, host cells methods of culture and a kit, classified in class 536, subclass23.1 and class 435, subclasses 320.1 and 325, for example.

III. Claims 21-22 and 32-37, drawn to methods of treatment using a protein, classified in class 514, subclass 2, for example.

IV. Claims 21-22 and 32-37, drawn to methods of treatment using a nucleic acid, classified in class 514, subclass 44, for example.

V. Claims 23-25 and 30-31, drawn to antibodies and compositions containing an antibody, classified in class 530, subclass 387.1 and class 424, subclass 130.1, for example.

VI. Claims 32-37, drawn to methods of treatment using an antibody, classified in class 424, subclass 130.1+, for example.

VII. Claims 26-27, drawn to a method for detecting antibodies and a kit, classified in class 435, subclass 7.2, for example.

VIII. Claims 28-29, drawn to methods for detecting Chlamydia and a kit, classified in class 435, subclass 7.2, for example.

IX. Claims 40-41, drawn to hybridization methods and a kit, classified in class 435, subclass 6.

Note: Claims 19-22, 25, 30-31, and 32-37 will be examined only to the extent that they read on the subject matter of the Groups set forth.

2. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, II, and V are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The protein of Group I is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group V is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II, and V can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group V can be used in immunoassays, and the protein of Group I can be used to make fusion proteins with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and V are patentably distinct from each other.

B) Inventions I and (III, VII, and VIII), are related as product and process of use. The

inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in materially different methods as evidenced by the distinct methods claimed in Groups III, VII, and VIII.

C) Inventions I and (IV, VI, and IX) are separate and distinct as the proteins of Group I are not used in the methods of Groups (IV, VI, and IX). As such, the inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

D) Inventions II and (IV, VII, and IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in materially different methods as evidenced by the distinct methods claimed in Groups IV, VII, and IX.

E) Inventions II and (III, VI, and VIII) are separate and distinct as the nucleic acids of Group II are not used in the methods of Groups (III, VI, and VIII). As such, the inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

D) Inventions V and (VI-VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in materially different methods as evidenced by the distinct methods claimed in Groups VI-VIII.

E) Inventions V and (III and IV) are separate and distinct as the antibodies of Group V are not used in the methods of Groups (III and IV). As such, the inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IX require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. A telephone call was made to Geraldine F. Baldwin on June 1, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
June 4, 2001

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600

6/4/01